

CLAIMS

What is claimed is:

1. A method of determining a duration of adequate immune memory induced by a vaccine for a disease in an animal, the method comprising:

5 (a) selecting a plurality of study animals from one or more clinics, where each animal has been vaccinated with the vaccine and where a time since a last vaccination date is at least about one year and the animal has been living in a field environment for at least about one year after the last vaccination date and each animal has a vaccine administration record;

10 (b) assigning each animal an indicator of immune memory, such that each animal that does not have a marker of immunity is assigned a first indicator and each animal that has the marker of immunity is assigned a second indicator; and

(c) determining the duration of adequate immune memory from: (i) the first indicator and the second indicator; and (ii) the vaccine administration record.

15 2. The method of claim 1, wherein the duration of adequate immune memory is determined from a duration of adequate immune memory estimation equation, said duration of adequate immune memory estimation equation derived by a logistic regression analysis of the first and the second indicators and the vaccine administration record.

3. The method of claim 1, wherein the animal is a companion animal.

20 4. The method of claim 1, wherein the animal is a dog or a cat.

5. The method of claim 1, wherein assigning each animal the indicator of immune memory comprises:

25 (a) evaluating a blood serum sample from each animal that has not shown clinical signs of the disease since the last vaccination date to detect an adequate antibody titer of at least about 2 for the disease;

(b) administering a booster dose of the vaccine to each animal that does not display the adequate antibody titer;

30 (c) evaluating a blood serum sample from each animal that has received the booster dose 3 days to 28 days following the booster dose to detect an adequate anamnestic response of at least about a 4-fold increase in serum antibody titer; and

(d) assigning the first indicator to each animal that displayed clinical signs of the disease since the last vaccination date or that neither displays the adequate antibody titer nor displays the adequate anamnestic response and assigning the second indicator to each animal that displays either the adequate antibody titer or the sufficient anamnestic response.

35 6. The method of claim 1, wherein assigning each animal the indicator of immune memory comprises:

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(a) evaluating a blood serum sample from each animal that has not shown clinical signs of the disease since the last vaccination date to detect a cellular immune response for the disease;

5 (b) assigning each animal that has displayed clinical signs of the disease since the last vaccination date or that does not display the cellular immune response the first indicator and assigning each animal that displays the cellular immune response the second indicator.

7. The method of claim 1, wherein determining the duration of adequate immune memory from the first and the second indicators and the vaccine administration  
10 record comprises:

(a) determining an enrollment date for each animal, the enrollment date being when evaluation of the animal to detect the marker of immunity was begun;

(b) assigning a start of study date as the enrollment date for a first animal of the plurality of animals enrolled in the study;

15 (c) assigning a variable  $X_j$  for each animal as a number of days between the start of study date and the enrollment date for the animal;

(d) assigning a variable  $X_i$  for each animal as a number of days between the last vaccination date for the animal and the enrollment date for the animal.

20 (e) determining the duration of adequate immune memory from a duration of adequate immune memory estimation equation, said duration of adequate immune memory estimation equation determined by a logistic regression analysis of the first and second indicators and the variables  $X_j$  and  $X_i$ .

8. The method of claim 7, wherein the duration of adequate immune memory estimation equation is in a form  $\text{logit}(E) = \beta_0 + \beta_1 X_{DI} + \beta_2 X_{CV} + C_k$  where:

25 E is a desired level of efficacy;

$X_{DI}$  is the duration of adequate immune memory;

$X_{CV}$  is a mean of  $X_j$ ;

$C_k$  is a constant representing a random effect to account for variation between the clinics and is derived by logistic regression; and

30  $\beta_0, \beta_1, \beta_2$  are constants derived by logistic regression.

9. The method of claim 8, wherein a model for the logistic regression to derive the values of  $C_k, \beta_0, \beta_1$ , and  $\beta_2$  is in a form  $\text{logit}(p) = \beta_0 + \beta_1 X_i + \beta_2 X_j + C_k$ ; where:

$\text{logit}(p)$  is a vector representing the immune statuses for the animals;

$C_k$  is the clinic from which each animal was selected.

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10. The method of claim 1, which comprises:

- a) assigning each animal that has displayed clinical signs of the disease since the last vaccination or that neither displays an adequate antibody titer, nor an adequate cellular titer nor an adequate anamnestic response the first indicator;
- 5 b) designating each animal which is not assigned the first indicator as either a high risk animal or a low risk animal;
- c) assigning each low risk animal that displays either a cellular immune response or that displays either the adequate antibody titer or the sufficient anamnestic response the second indicator;
- 10 d) assigning each high risk animal that has no history of the disease in question and where there is evidence of prevalence of the disease in question in the region the second indicator; and
- e) assigning each high risk animal that has no history of the disease in question that displays either the cellular immune response, or the adequate antibody titer or the sufficient anamnestic response, the second indicator.
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